

**K222304 Sonata Transcervical Fibroid Ablation System 2.2**Nov 8, 2022  
99 days to decisionK222304 · Product code: **KNF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222304/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF)
Date received	Aug 1, 2022
Decision date	Nov 8, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gynesonics, Inc.</b>
Location	Redwood City, CA, US
Contact	Diane King
510(k) history	8 submissions · 8 cleared · 2006-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222304/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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